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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,113	03/22/2000	Joseph R. Byrum	38-21(15761)B (16517.001)	4899
27161	7590	05/06/2004	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/531,113	Applicant(s) BYRUM ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/10/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application has been transferred from Examiner Arun Chakrabarti of Art Unit 1634 to Examiner Cynthia Wilder of Art Unit 1637. All further correspondence should be directed to Examiner Cynthia Wilder whose contact information appear at the end of this Office Action.
2. Appellant's brief filed on March 10, 2004 is acknowledged. Claims 1, 8-13 are pending. Claims 2-7 have been canceled. All of the arguments have been thoroughly reviewed and considered, but are deemed moot in view of the new grounds of rejections. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

4. All previous rejections are withdrawn in view of the new grounds of rejections.

Claim Rejections - 35 USC § 101 (Lack of Utility)

5. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Application under 35 U.S.C. 112, first paragraph, "Written Description" requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

Credible Utility" - Where an Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if

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the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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6. Claims 1, 8-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed subject matter is not supported by a specific, substantial or a well established utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

The claimed invention is drawn to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981 or a substantially purified nucleic acid molecule comprising a sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. As noted earlier, a well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of the a material, alone or take with the knowledge of one skilled in the art.. The specification discloses a number of general utilities for the nucleic acid molecule disclosed herein. For example, the specification discloses that the nucleic acid molecules may be used as molecule tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 15), in marker-assisted breeding programs (page 16), as antibodies (page 16), as primer and probes for the isolation of full length cDNAs or genes (page 28), in mutation detection (page 37), in the identification of polymorphism (page 38), as molecular markers (page 50), genetic mapping studies (page 49), in DNA-protein interaction (page

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52) in methods of identifying chromosomes with translocation (page 52), in method of protein-protein interaction (page 60), in microarray based methods (page 54), in site directed mutagenesis (page 56) and in methods of transformation (page 61). None of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed. Likewise no direct connection is made between the claimed sequence or any of the numerous utilities claimed. The examples beginning at page 85 do not provide any disclosure which demonstrates the functionality of the claimed nucleic acid sequence or fragments thereof or complement thereof as for example, probes and/or primers to detect a mutation or as marker to determine gene function. Thus, further research is required to determine the specific utility of the claimed nucleic acid sequence.

Further, the claimed nucleic acid and/or the encoded protein are not supported by a substantially utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and

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substantial utilities. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the claimed use of the nucleic acid the instant specification is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid or the encoded protein such that another non-asserted utility would be well established for the compounds.

Claims 1-16 and 35-38 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981 or a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof or a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. The disclosure of fragments or complements thereof of SEQ ID NO: 5981 encompass a large genus of nucleic acid sequence species that are not described in the specification or examples starting at page 85. This large genus of nucleic acid species is only represented in the specification by the name SEQ ID NO: 5891. This applicant has express possession of only one nucleic acid species in a genus which comprises hundreds of millions of different possibilities. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. The written description guidelines note regarding such genus/species situation that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed" (see: Federal Register; December 21, 1999 (Volume 64, Number 244), revised guidelines for written description). Here, no common element or attributes of the sequences are disclosed and no structural limitations or requirements which

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provide guidance on the identification of sequences which meet these functional limitations is provided. Further, there is no methodology presented to determine such common elements or attributes. Further, there is no description portions of the nucleic acids. Likewise, these claims expressly encompass genomic nucleic acids and not even complete cDNA sequences. Additionally, with regard to the written description, claims additionally include modifications permitted by the 90% to 99% language or fragment thereof or complement thereof for which no written description is provided in the specification. As set forth by the Court in *Vas Cath Inc. V. Manhurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of claims 1, 8-13 of the specification fails to show that applicant was, in fact, "in possession of the claimed invention", at the time the application for patent was filed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (US 6,476,208 B1, filing date March 20, 2000). Regarding claims 1, 8-13, Cohen teaches a nucleic acid sequence molecule comprising a sequence that is a fragment of or a complement of the sequence of SEQ ID NO: 5981 (see SEQ ID NO: 129). Therefore, Cohen et al. meets the limitations of claims 1, 8-13 of the instant invention.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Wilder
CYNTHIA WILDER
PATENT EXAMINER
5/4/2004